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**Patent and Trademark Office**

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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/447,820 05/23/95 EKINS

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18M1/1016  
DANN DORFMAN HERRELL AND SKILLMAN  
SUITE 720  
1601 MARKET STREET  
PHILADELPHIA PA 19103-2307

EXAMINER

WOODWARD, M

ART UNIT

PAPER NUMBER

1815

4

DATE MAILED: 10/16/96

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 7/12/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.                 | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.                  |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/> _____  |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-3 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2. ☐ Claims \_\_\_\_\_ have been cancelled.

3. ☐ Claims \_\_\_\_\_ are allowed.

4. ☒ Claims 1-3 are rejected.

5. ☐ Claims \_\_\_\_\_ are objected to.

6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on: \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

**EXAMINER'S ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1815**.

5           **Applicant is advised of possible benefits under 35 U.S.C. § 119, wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country.**

10           The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

20           A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

25           Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30           Claims 1-3 are rejected under the judicially created doctrine of double patenting over claims 1-17 of U. S. Patent No. 5,432,099 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

          The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are

claiming common subject matter, as follows: The instant claims specifically recite what appears to be a preferred embodiment wherein the capture reagent is detectably labelled so as to preclude the necessity for rigid control of the amount of capture reagent immobilized.

5 Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

10 Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,432,099 in view of Chen et al. (4,385,126). Claims 1-3 explicitly recite the employment of a detectable label on the immobilized binding agent which feature is not explicitly recited in the claims of '099. However, the advantages of employing a detectably labelled binding agent, e.g.,  
15 internal calibration, quality control, et cetera, are explicitly taught by Chen et al. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the methods of the '099 patent by the inclusion of immobilized labelled binding members for the advantages taught by Chen et al.

20 The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

25 A person shall be entitled to a patent unless --  
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. § 102(a) as being clearly

5 anticipated by Ekins et al. (1989).

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ekins (WO 88/01058).

10 Ekins discloses a volume independent immunoassay wherein 1-2% or less of total analyte present is bound by the analyte receptor. Ekins discloses detection of both the amount of analyte receptor present and the amount of analyte through the use of detectable labels, e.g. radioactive or fluorescent.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

15 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at  
20 the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 3 is rejected under 35 U.S.C. § 103 as being unpatentable over  
30 Ekins (WO 88/01058) in view of the commercial availability of the Bio-Rad Laserssharp MRC 500.

As set forth above Ekins discloses the claimed immunoassay format.

Ekins discloses several means of detection with the exception of a laser scanning confocal microscope. The analytical device of Figure 2 is suggestive of a microscope slide and in view of the advantages of confocal microscopy it would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the claimed methods employing a laser scanning confocal microscope such as the Bio-Rad Lasersharp MRC 500.

Claims 1 and 2 are rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Ekins (WO 84/01031) and Chen et al. (US 4,385,126).

Ekins discloses a volume independent immunoassay wherein insignificant amounts of analyte are bound. No particular value above which significant binding is deemed to occur is specifically recited, however, example 2 appears to meet the condition that no more than 0.1 V/K moles of binding agent be present. Ekins does not disclose labelling the binding agent.

However, the advantages of employing a detectably labelled binding agent, e.g., internal calibration, quality control, et cetera, are explicitly taught by Chen et al. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the methods of Ekins by the inclusion of immobilized labelled binding members for the advantages taught by Chen et al.

Ekins further suggests that fluorescent labels be employed rather than radioactive isotopes. A similar suggestion and examples are present in Chen et al. Thus, in view of the suggestions and teachings of both Ekins and Chen et al. it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ fluorescently labelled reagents.

Claims 1-3 are rejected under 35 U.S.C. § 103 as being unpatentable over

the combined teachings of Ekins (WO 84/01031) and Chen et al. (US 4,385,126) as applied to claims 1 and 2 above, and further in view of the commercial availability of the Bio-Rad Laserssharp MRC 500.

Ekins and Chen et al. have been discussed supra. Ekins also suggests multiple-analyte assays relying on the scanning of the distribution of fluorescent labels (see page 5). In view of the advantages of confocal microscopy it would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the claimed methods employing a laser scanning confocal microscope such as the Bio-Rad Laserssharp MRC 500.


White et al. (1987) is made of record as it is exemplary of the level of ordinary skill in the art prior to the time the instant invention was made with respect to confocal microscopy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MP Woodward whose telephone number is (703) 308-3890. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

The fax phone number for this Art Unit is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
MICHAEL P. WOODWARD  
PRIMARY EXAMINER  
GROUP 1800

October 14, 1996